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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,481	12/12/2003	Claus Garbe	WWELL73.008C1	2551

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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,481	GARBE ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,6,31,33,35,37,39,41,43,45 and 47* is/are pending in the application.

4a) Of the above claim(s) *6,31,33,35,41 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,37,39,43 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed on August 22, 2005 is acknowledged. Claims 2, 4, 37, 39, 43 and 45 are pending and under consideration. Claims 6, 31, 33, 35, 41 and 47 have been withdrawn as they are drawn to non-elected subject matter. Claims 1, 3, 5, 7-30, 32, 34, 36, 38, 40, 42, 44 and 46 have been canceled and withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

2. It should be noted that the restriction requirement dated May 20, 2005 was done in error. Consequently, the election should have had three groups instead of two. For the record the groupings for the election restriction is as follows:

I. Claims 1-11 and 36-47, drawn to a microbiallly active peptide, classified in class 530, subclass 326.

II. Claims 12-29, drawn to a nucleic acid molecule, classified in class 536, subclass 23.4.

III Claims 30-35, drawn to a method for protecting and/or treating human skin against microorganisms, classified in class 530, subclass 350.

Please note that should the peptide be deemed allowable the method of claims 31-35 may be considered for rejoinder.

3. Applicant's election with traverse of Group I is acknowledged. The traversal is on the ground that a) the claims should be examined together because claims 31-35 which are drawn to a method of using the microbially active peptide were restricted out of group I in error and b) applicant elected species of SEQ ID NO: 2 and traverses: sequences of SEQ ID NO: 2 and SEQ ID NO: 3 stating that they are not structurally different, as they only differ by 1 amino acid.

It is the examiners position that the sequences of SEQ ID NO: 2 and SEQ ID NO: 3 are different peptides with different effects. The examiner directs applicant to Figure 3 (0081; SEQ ID 2) and Figure 5 (0083; SEQ ID 3) where the two sequences are purportedly similar, but yet have very different effects. Moreover, the presence or absence of 1 amino acid makes a difference in the two sequences. The state of the art is one that submits that there is no guidance provided as to which amino acids can be deleted and the polypeptide would retain its biological function. Since the amino acid sequence of the polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity requires a knowledge with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the polypeptide's structure relates to function. However, the problem of the prediction of polypeptide structure from mere sequence data of a single polypeptide and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide and finally what changes can be tolerated with respect thereto is extremely

complex and outside of the realm of routine experimentation. There is no guidance as to what amino acids may not be changed without causing a detrimental effect.

This is further demonstrated by Thomas E. Creighton, in his book, "Proteins: Structures and Molecular Properties, 1984", (pages 314-315), which teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause mutant hemoglobin to have lower stabilities due to any of several causes:

1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge; 2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a Praline residue, which must distort the alpha-helix; 3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

Thomas E. Creighton, in his book "Protein Structure: A Practical Approach, 1989; pages 184-186" teaches that present day site directed mutagenesis of a gene allows any amino acids in a protein sequence to be changed to any other, as well as introducing deletions and insertions". The reference goes on to teach that it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect.

Nosoh, Y. et al in "Protein Stability and Stabilization through Protein Engineering, 1991" (chapter 7, page 197, second paragraph) adds support to Thomas E. Creighton, by teaching that results so far accumulated on the stability and stabilization of proteins

appear to indicate that the strategy for stabilizing proteins differ from protein to protein and that any generalized mechanisms for protein stability have not yet been presented. Applicants argument has been considered, but is not found persuasive. Claims 2, 4, 37, 39, 43 and 45 are directed to a peptide and claims 31-35 are directed to a method. These are different statutory classes of invention and MPEP § 806.05(f) states that these inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process. In the case at hand the examiner has averred that the product as claimed can be used for something other than the instantly claimed method. The examiner has further established a prima facie case of a burden by establishing a different classification for these two different statutory groups of invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Priority

4. The examiner acknowledges applicants submission of the translated foreign application and thereby grants applicant benefit of foreign priority under 35 U.S.C. 119(a)-(d).

Objections Withdrawn

5. In view of applicant's response, the objection to the specification, page 6, has been withdrawn.

6. In view of applicant's response, the claim objections, page 6-7, have been withdrawn.

Rejections Withdrawn

7. In view of applicant's response, the rejection of claims 1-4, 7-11, 36-39 and 42-45 under 35 U.S.C. 102(a) has been withdrawn.

Rejections Maintained

8. The rejection of claims 2, 4, 37, 39, 43 and 45 under 35 U.S.C. 102(b) is maintained for the reasons set forth in the previous office action, page 7.

The rejection was on the ground that Akerblom et al disclose the protein DCD, which was identified in SEQ ID NO: 1. The expression of DCD in sweat glands was demonstrated using the dot blot method. Akerblom et al disclose a polynucleotide and amino acid sequence (SEQ ID NO: 2). SEQ ID NO: 2 is identical to the SEQ ID NO: 1 disclosed in the present application (column 29-30). Moreover Akerblom et al disclose that modifications of the polypeptides include, but are not limited to acetylation, carboxylation, glycosylation, phosphorylation, lipidation and acylation. Post-translational processing which cleaves a "prepro" form of the protein may also be important for correct insertion, folding and/or function (column 11, lines 14-20). Additionally, Akerblom et al disclose that a fusion protein may be engineered to contain a cleavage site located between a HCAP sequence and the heterologous protein sequence (column 8, lines 42-48). Akerblom et al disclose that it can be designed with signal sequences in addition to other recombinant constructions (column 13, lines 14-20). Lastly, Akerblom et al disclose the use of the isolated protein in pharmaceutical compositions. Administration of the composition is accomplished orally or parenterally and can include topical delivery. Pharmaceutical compositions suitable for use in the present invention include compositions where the active ingredients are contained in an effective amount to achieve the intended purpose (column 22, lines 1-6). Inherently, the antimicrobially active peptide secreted from sweat glands is the same as the claimed composition because Akerblom et al disclose an identical peptide and amino acid sequence, which comprises SEQ ID NO: 1 and fragments thereof (SEQ ID NO: 2).

Applicant urges that a) Akerblom et al does not disclose a peptide comprising a maximum of 50 amino acid residues from the C-terminal region of this peptide, b) Akerblom et al does not disclose that this fragment has antimicrobial properties and c) Akerblom et al does not anticipate currently amended claims 2, 4, 37, 39, 43 and 45.

It is the examiners position that claims 2, 4, 37, 39, 43 and 45 are drawn to an antimicrobially active peptide comprising a DCD protein fragment, wherein the fragment comprises a maximum of 50 amino acid residues from the C-terminal region of DCD. The term comprising is viewed as open claim language implying that other things may be present; in this case other amino acids can be present. SEQ ID NO: 2 is a peptide that comprises 50 amino acid residues. The examiner is not viewing the claim language to only incorporate the 50 amino acids claimed, but to incorporate the 50 amino acids and others. The peptide of Akerblom et al comprises the claimed fragment. There is nothing on the record via a side-by-side comparison to show that the peptide of the prior art would not have the same activity of the instantly claim peptide. Since the fragment is present, the peptide would inherently have antimicrobial activity.

New grounds of Rejection

Specification/Figures

9. The disclosure is objected to because of the following informalities: The figures, specifically Figure 3 (0081; SEQ ID 2) and Figure 5 (0083; SEQ ID 3), do not correlate to the brief description. The examiner is not clear what the bar graph represents. What are the shadings representative of?

Appropriate correction is required.

Claim Objections

10. Claim 1 is objected to because of the following informalities: On first sight the acronym "DCD" should be followed by dermcidin.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT

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